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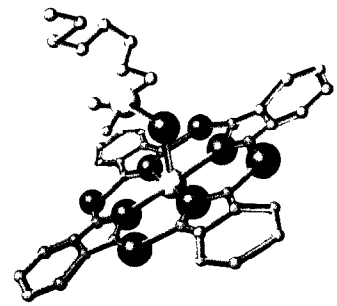

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December 14, 2005

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Subject **Docket No. 2001D-0044** *Draft Guidance for Industry and FDA Staff Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications.*

Dear Sir/Madam:

Biosite Incorporated is pleased to submit its comments on the captioned Draft Guidance document setting out FDA's current thinking about requirements for *in vitro* diagnostic products (IVDs) to be recategorized from nonwaived to waived status under CLIA. Biosite is vitally interested in the policies described in this draft Guidance because it is among those small, rapidly growing, and highly innovative companies that invests exclusively in the development and worldwide marketing of IVDs for use at the point-of-care (POC) in highly challenging clinical situations, e.g., requiring only minutes to obtain emergency situation test results for drug overdoses, diagnosing heart attacks, and distinguishing heart failure from other problems that share symptomology.

Biosite's rapid test systems are used daily in more than one-half of all hospitals in the U.S., ranging in size from the largest urban settings to the most rural and remote clinics. We believe that, to assure access to timely test results across all of this country, Biosite must design test systems that are so simple and reliable that they can be used by a variety of healthcare professionals asked to run a test in a healthcare setting. Likewise, we believe that all of the federal agencies charged with implementing clinical laboratory oversight under CLIA have an absolute obligation to match our investment in innovation with new, pragmatic thinking about how their decisions help or hinder the access to and use of these essential laboratory testing capabilities.

We are, therefore, disappointed in the thinking reflected in FDA's Draft Guidance on CLIA waiver criteria. Biosite had an opportunity to participate in the industrywide evaluation of this draft Guidance document, including the final letter that was submitted by AdvaMed that reflects a very strong consensus among IVD companies. This draft Guidance must be withdrawn. The federal agencies that participate in CLIA policymaking simply have to start over in devising CLIA waiver criteria that are consistent with Congressional intent and meet our collective goal to address clinicians' and patients' need for rapid and reliable point-of-care test systems without placing undue burdens on the developers of these essential technologies.

One of the underlying problems in the agencies' thinking in recent years is that a laboratory test must possess a superior performance threshold for eligibility for waiver. Any test that is cleared by the FDA should be eligible for waiver so long as the simplicity and little "likelihood" of error "*by the user*" criteria can be met. There is little recognition or value given to providing testing information in a timely fashion so that clinicians can make better decisions and patients can share

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in that decision-making, often in one physician visit. Ask any patient, or parent of young children, with flu-like symptoms this winter whether they would prefer highly reliable influenza tests results in 10 minutes during the physician visit or bulletproof laboratory results right down to the viral subtype from a reference laboratory . . .in about two weeks. Patients and patient care require that all possible testing be made as broadly accessible as possible for routine diagnoses or seasonal outbreaks. Yet nothing in this draft Guidance reflects the needed agencies' commitment to make this access happen

We have attached to this letter a published evaluation of multiple ways to diagnose and manage women at risk for infection with Chlamydia trachomatis. No commentary is intended on the individual IVD test systems or central laboratory methods compared. While it is clear that all of the tests and patient management strategies considered can provide useful information, this analysis shows that only rapid testing can provide the most effective and efficient care in the urban STD clinic context being evaluated. We would welcome more such contextual thinking in FDA's future consideration of waiver criteria. (Kenneth Webb, MD, the author of this comparative analysis, may have been the Medical Director of an IVD company at the time he did this analysis, but his work stands the test of independent journal review and his credentials as a practicing pediatrician and published health economist from Stanford are uncontestable.)

We appreciate how difficult it must be for the same FDA scientists that interpret the food and drug laws every day to shift subjects for purposes of implementing the very different CLIA waiver standards. That shift is not reflected in this draft Guidance. We urge immediate withdrawal of this document and public notice from FDA leadership that established precedents should be followed in seeking recategorization to waived status while FDA prepares for new deliberations with all of the stakeholders next year.

Sincerely,

Robin Weiner

Robin Weiner
Vice President,
Regulatory and Government Affairs
Biosite Incorporated

Enclosure